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CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1069

Introduced by Assembly Member Gordon
(Coauthors: Assembly Members Chu, Low, and Mark Stone)
(Coauthors: Senators Beall and Wieckowski)

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as amended, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including a pharmacy that is owned by, or contracts with, the county, may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. ~~Existing law requires a county that establishes a depository and redistribution program to develop written procedures for, among other things, establishing eligibility for medically indigent patients who may participate in the program, and ensuring that patients eligible for the program are not charged for any medications provided under the program. Existing law also prohibits the donation of controlled substances to the repository~~

~~and distribution program.~~ Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards, and that includes lot numbers and expiration dates, is eligible for donation to the program. ~~Existing law authorizes a county-owned pharmacy participating in the program to transfer eligible donated medication to a county-owned pharmacy participating in the program within another adjacent county, as specified.~~ Existing law prohibits medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity. Existing law requires medication donated to the repository and distribution program to be maintained in the donated packaging units.

~~This bill would authorize an entity participating in the medication repository and distribution program to transfer eligible donated medication to a participating entity in any other county, as specified. The bill would generally prohibit an entity from transferring more than 15% of its donated medications annually. The bill would authorize medication donated to a medication repository and distribution program to be maintained in new, properly labeled containers, as specified. The bill would prohibit donated medication from being repackaged more than 2 times. This bill would also make a technical, nonsubstantive change to these provisions.~~

This bill would authorize a pharmacy that exists solely to operate the repository and distribution program to repackage a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population. The bill would require a pharmacy that repackages medication to have repackaging policies and procedures in place for identifying and recalling medications.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 150204 of the Health and Safety Code
- 2 is amended to read:
- 3 150204. (a) (1) A county may establish, by an action of the
- 4 county board of supervisors or by an action of the public health
- 5 officer of the county, as directed by the county board of
- 6 supervisors, a repository and distribution program for purposes of
- 7 this division. The county shall advise the California State Board

1 of Pharmacy within 30 days from the date it establishes a repository
2 and distribution program.

3 (2) Only an eligible entity, pursuant to Section 150201, may
4 participate in this program to dispense medication donated to the
5 drug repository and distribution program.

6 (3) An eligible entity that seeks to participate in the program
7 shall inform the county health department and the California State
8 Board of Pharmacy in writing of its intent to participate in the
9 program. An eligible entity may not participate in the program
10 until it has received written or electronic documentation from the
11 county health department confirming that the department has
12 received its notice of intent.

13 (4) (A) A participating entity shall disclose to the county health
14 department on a quarterly basis the name and location of the source
15 of all donated medication it receives.

16 (B) A participating primary care clinic, as described in Section
17 150201, shall disclose to the county health department the name
18 of the licensed physician who shall be accountable to the California
19 State Board of Pharmacy for the clinic's program operations
20 pursuant to this division. This physician shall be the professional
21 director, as defined in subdivision (c) of Section 4182 of the
22 Business and Professions Code.

23 (C) The county board of supervisors or public health officer of
24 the county shall, upon request, make available to the California
25 State Board of Pharmacy the information in this division.

26 (5) The county board of supervisors, the public health officer
27 of the county, and the California State Board of Pharmacy may
28 prohibit an eligible or participating entity from participating in the
29 program if the entity does not comply with the provisions of the
30 program, pursuant to this division. If the county board of
31 supervisors, the public health officer of the county, or the California
32 State Board of Pharmacy prohibits an eligible or participating
33 entity from participating in the program, it shall provide written
34 notice to the prohibited entity within 15 days of making this
35 determination. The county board of supervisors, the public health
36 officer of the county, and the California State Board of Pharmacy
37 shall ensure that this notice also is provided to one another.

38 (b) A county that elects to establish a repository and distribution
39 program pursuant to this division shall establish written procedures
40 for, at a minimum, all of the following:

1 (1) Establishing eligibility for medically indigent patients who
2 may participate in the program.

3 (2) Ensuring that patients eligible for the program shall not be
4 charged for any medications provided under the program.

5 (3) Developing a formulary of medications appropriate for the
6 repository and distribution program.

7 (4) Ensuring proper safety and management of any medications
8 collected by and maintained under the authority of a participating
9 entity.

10 (5) Ensuring the privacy of individuals for whom the medication
11 was originally prescribed.

12 (c) Any medication donated to the repository and distribution
13 program shall comply with the requirements specified in this
14 division. Medication donated to the repository and distribution
15 program shall meet all of the following criteria:

16 (1) The medication shall not be a controlled substance.

17 (2) The medication shall not have been adulterated, misbranded,
18 or stored under conditions contrary to standards set by the United
19 States Pharmacopoeia (USP) or the product manufacturer.

20 (3) The medication shall not have been in the possession of a
21 patient or any individual member of the public, and in the case of
22 medications donated by a health or care facility, as described in
23 Section 150202, shall have been under the control of a staff
24 member of the health or care facility who is licensed in California
25 as a health care professional or has completed, at a minimum, the
26 training requirements specified in Section 1569.69.

27 (d) (1) Only medication that is donated in unopened,
28 tamper-evident packaging or modified unit dose containers that
29 meet USP standards is eligible for donation to the repository and
30 distribution program, provided lot numbers and expiration dates
31 are affixed. Medication donated in opened containers shall not be
32 dispensed by the repository and distribution program, and once
33 identified, shall be quarantined immediately and handled and
34 disposed of in accordance with the Medical Waste Management
35 Act (Part 14 (commencing with Section 117600) of Division 104).

36 (2) (A) A medication that is the subject of a United States Food
37 and Drug Administration managed risk evaluation and mitigation
38 strategy pursuant to Section 355-1 of Title 21 of the United States
39 Code shall not be donated if this inventory transfer is prohibited

1 by that strategy, or if the inventory transfer requires prior
2 authorization from the manufacturer of the medication.

3 (B) A medication that is the subject of a United States Food and
4 Drug Administration managed risk evaluation and mitigation
5 strategy pursuant to Section 355-1 of Title 21 of the United States
6 Code, the donation of which is not prohibited pursuant to
7 subparagraph (A), shall be managed and dispensed according to
8 the requirements of that strategy.

9 (e) A pharmacist or physician at a participating entity shall use
10 his or her professional judgment in determining whether donated
11 medication meets the standards of this division before accepting
12 or dispensing any medication under the repository and distribution
13 program.

14 (f) A pharmacist or physician shall adhere to standard pharmacy
15 practices, as required by state and federal law, when dispensing
16 all medications.

17 (g) Medication that is donated to the repository and distribution
18 program shall be handled in the following ways:

19 (1) Dispensed to an eligible patient.

20 (2) Destroyed.

21 (3) Returned to a reverse distributor or licensed waste hauler.

22 ~~(4) (A) Transferred to another participating entity within the~~
23 ~~county to be dispensed to eligible patients pursuant to this division.~~
24 ~~Notwithstanding this paragraph, a participating entity may transfer~~
25 ~~eligible donated medication to a participating entity within another~~
26 ~~county that has adopted a program pursuant to this division, if the~~
27 ~~participating entities transferring the medication have a written~~
28 ~~agreement that outlines protocols and procedures for safe and~~
29 ~~appropriate drug transfer that are consistent with this division. A~~
30 ~~participating entity shall not transfer more than 15 percent of its~~
31 ~~donated medications annually unless the transfer is performed~~
32 ~~pursuant to Section 4126.5 of the Business and Professions Code.~~

33 *(4) (A) Transferred to another participating entity within the*
34 *county to be dispensed to eligible patients pursuant to this division.*
35 *Notwithstanding this paragraph, a participating county-owned*
36 *pharmacy may transfer eligible donated medication to a*
37 *participating county-owned pharmacy within another adjacent*
38 *county that has adopted a program pursuant to this division, if the*
39 *pharmacies transferring the medication have a written agreement*
40 *between the entities that outlines protocols and procedures for*

1 *safe and appropriate drug transfer that are consistent with this*
2 *division.*

3 (B) Medication donated under this division shall not be
4 transferred by any participating entity more than once, and after
5 it has been transferred, shall be dispensed to an eligible patient,
6 destroyed, or returned to a reverse distributor or licensed waste
7 hauler.

8 (C) Medication transferred pursuant to this paragraph shall be
9 transferred with documentation that identifies the drug name,
10 strength, and quantity of the medication, and the donation facility
11 from where the medication originated shall be identified on
12 medication packaging or in accompanying documentation. The
13 document shall include a statement that the medication may not
14 be transferred to another participating entity and must be handled
15 pursuant to subparagraph (B). A copy of this document shall be
16 kept by the participating entity transferring the medication and the
17 participating entity receiving the medication.

18 (h) Medication that is donated to the repository and distribution
19 program that does not meet the requirements of this division shall
20 not be distributed or transferred under this program and shall be
21 either destroyed or returned to a reverse distributor. Donated
22 medication that does not meet the requirements of this division
23 shall not be sold, dispensed, or otherwise transferred to any other
24 entity.

25 (i) ~~(1) Medication—Except as provided in paragraph (2),~~
26 ~~medication~~ donated to the repository and distribution program
27 shall be maintained in the donated packaging units ~~or new, properly~~
28 ~~labeled containers~~ until dispensed to an eligible patient under this
29 program, who presents a valid prescription. When dispensed to an
30 eligible patient under this program, the medication shall be in a
31 new and properly labeled container, specific to the eligible patient
32 and ensuring the privacy of the individuals for whom the
33 medication was initially dispensed. Expired medication shall not
34 be dispensed. ~~Donated medication shall not be repackaged more~~
35 ~~than two times. Nothing in this section requires donated medication~~
36 ~~to be repackaged two times.~~

37 ~~(2) All of the following requirements shall be satisfied when~~
38 ~~repackaging donated medication:~~

39 ~~(A) Medication shall be repackaged into a container that holds~~
40 ~~an individual prescription for a supply of no more than 90 days.~~

1 ~~(B) Repackaged medication shall be identifiable as donated~~
2 ~~medication.~~

3 ~~(C) Repackaged medication shall be labeled with all of the~~
4 ~~following:~~

5 ~~(i) All applicable lot numbers.~~

6 ~~(ii) The earliest expiration date.~~

7 ~~(iii) The number of times that the medication has been~~
8 ~~repackaged.~~

9 *(2) A pharmacy that exists solely to operate the repository and*
10 *distribution program may repack a reasonable quantity of*
11 *donated medicine in anticipation of dispensing the medicine to its*
12 *patient population. The pharmacy shall have repackaging policies*
13 *and procedures in place for identifying and recalling medications.*

14 (j) Medication donated to the repository and distribution program
15 shall be segregated from the participating entity's other drug stock
16 by physical means, for purposes including, but not limited to,
17 inventory, accounting, and inspection.

18 (k) A participating entity shall keep complete records of the
19 acquisition and disposition of medication donated to, and
20 transferred, dispensed, and destroyed under, the repository and
21 distribution program. These records shall be kept separate from
22 the participating entity's other acquisition and disposition records
23 and shall conform to the Pharmacy Law (Chapter 9 (commencing
24 with Section 4000) of Division 2 of the Business and Professions
25 Code), including being readily retrievable.

26 (l) Local and county protocols established pursuant to this
27 division shall conform to the Pharmacy Law regarding packaging,
28 transporting, storing, and dispensing all medications.

29 (m) County protocols established for packaging, transporting,
30 storing, and dispensing medications that require refrigeration,
31 including, but not limited to, any biological product as defined in
32 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
33 an intravenously injected drug, or an infused drug, shall include
34 specific procedures to ensure that these medications are packaged,
35 transported, stored, and dispensed at appropriate temperatures and
36 in accordance with USP standards and the Pharmacy Law.

37 (n) Notwithstanding any other provision of law, a participating
38 entity shall follow the same procedural drug pedigree requirements

- 1 for donated drugs as it would follow for drugs purchased from a
- 2 wholesaler or directly from a drug manufacturer.

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